

510(k) Summary

Date: 21 May 2014

Sponsor: Nexxt Spine
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Contact Person: Eric Lintula, Director of Engineering and Regulatory Affairs

Trade Names: Inertia[®], Honour[™], Facet Fixx[™], Inertia[™] MIS, Struxxure[™]

Common Names: Pedicle screw system, anterior cervical system, vertebral body replacement system, interbody fusion system and facet screw system

Device Classification, Classification, Regulations, Names & Product Codes: Inertia[®] and Inertia[™] MIS
888.3050, Spinal interlaminar fixation orthosis, KWP, Class II
888.3070, Pedicle screw spinal system, MNI & MNH; Class II
Honour[™]
888.3060, Spinal intervertebral body fixation orthosis, MQP, Class II
888.3080, Intervertebral body fusion device, ODP & MAX, Class II
Facet Fixx[™]
Unclassified, System, facet screw spinal device, MRW
Struxxure[™]
888.3060, Spinal intervertebral body fixation orthosis, KWQ, Class II

Submission Purpose: This submission modifies the sterilization and packaging state of the Nexxt Spine spinal systems implants. The Inertia[®], Honour[™], Facet Fixx[™] and Struxxure[™] implants will be optionally available as sterile.

Device Descriptions: The Inertia[®] Pedicle Screw System consists of rods, polyaxial screws and set screws. Rods are available in either straight or pre-contoured (curved) forms and in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations. Set screws are used to fasten the rod and polyaxial screw.

The HONOUR[™] Spacer System is a collection of radiolucent cage devices. The basic shape of these implants is a structural column. The superior and inferior surfaces are open with serrations to facilitate implant stability. The implants are available in an assortment of height, length, width and anteroposterior angulation combinations to accommodate a variety of anatomic requirements.

The Facet Fixx[™] System is a posterior facet spinal fixation system consisting of screws with and without washers. The cannulated screw is offered partially or fully threaded in various diameter and length combinations.

Struxxure[™] consists of plates and screws in a variety of sizes. Plates from 1- to 5-levels are offered. Fixed and variable angle screws are available in two diameters in both self-tapping and self-drilling versions.

Intended Use: The Intended Use for each cleared spinal system is unchanged.

The Inertia[®] Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

When used as a cervical intervertebral fusion device, the **HONOUR™ devices** are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine (e.g., the Blade® Anterior Cervical Plate System).

When used as a lumbar intervertebral fusion device, the **HONOUR™ devices** are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous graft and with supplemental fixation systems cleared for use in the lumbar spine (e.g., the Inertia® Pedicle Screw System).

When used as a vertebral body replacement device, the **HONOUR™ devices** are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation systems cleared for use in the thoracolumbar spine (e.g., the Inertia® Pedicle Screw System).

The **Facet Fixx™ System** is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle. For translaminar facet fixation, the screws are inserted through the lateral aspect of the spinous process, through the lamina, through the inferior articular process, across the facet joint and into the pedicle.

The **Facet Fixx System** is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from C2 to S1 inclusive. The **Facet Fixx System** is indicated for treatment of any or all of the following:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origins confirmed by history and radiographic studies
- Degenerative disease of the facets with instability
- Trauma (i.e. fracture or dislocation)
- Spondylolisthesis
- Spondylolysis
- Pseudarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity

The **Struxure™ System** is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Materials:

Nexxt Spine spinal systems implants are manufactured from a variety of medical grade materials including titanium alloy (Ti-6Al-4V ELI) per ASTM F136, CP Titanium (Grade 2 or 4) per ASTM F67, Zeniva® ZA-500 polyetheretherketone per ASTM F-2026 or tantalum per ASTM F-560.

Predicate Devices:

Inertia® Pedicle Screw System, Nexxt Spine, K090984, K101278 & K132412
Honour™ Spacer System, Nexxt Spine, K120345
Facet Fixx™, Nexxt Spine, K131417
Struxure™ Anterior Cervical Plate and Screws, Nexxt Spine, K133475

Performance Data:

Performance data is not provided in this submission.

Technological Characteristics:

Each spinal system implant possesses the identical technological characteristics as its respective predicate implant. These include:

- basic design,
- material,
- mode of operation,
- sizing and
- anatomic location.

Therefore the fundamental scientific technology of each Nexxt Spine spinal system implant is the same as the previously cleared Nexxt Spine spinal system implant.

Conclusion:

In comparison to the predicate devices, the Nexxt Spine spinal system implants have

- the same intended use (as described above),
- the same technological characteristics (as described above)

Therefore the Nexxt Spine spinal system implants can be found substantially equivalent to the predicate Nexxt Spine spinal system implants.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2014

Nexxt Spine, LLC
% Karen E. Warden, Ph.D.
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026

Re: K141376

Trade/Device Name: Inertia® pedicle screw system, Inertia™ MIS pedicle screw system, Honour™ interbody fusion system, Facet Fixx™ facet screw system, and StruXXure™ anterior cervical system

Regulation Number: 21 CFR 888.3070

Regulation Name: Pedicle screw spinal system

Regulatory Class: Class II

Product Code: MNH, MNI, KWP, MQP, ODP, MAX, MRW, KWQ

Dated: May 21, 2014

Received: May 28, 2014

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Page 2 – Karen E. Warden, Ph.D.

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K141376

Device Name
Inertia® and Inertia™ MIS pedicle screw systems

Indications for Use (Describe)

The Inertia™ Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; spinal stenosis; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Zane W. Wyatt
Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRASTaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)
K141376

Device Name
HONOUR™ interbody fusion system

Indications for Use (Describe)

When used as a cervical intervertebral fusion device, the HONOUR™ devices are indicated for use at one level in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the cervical spine (e.g., the Blade® Anterior Cervical Plate System).

When used as a lumbar intervertebral fusion device, the HONOUR™ devices are indicated for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autogenous graft and with supplemental fixation systems cleared for use in the lumbar spine (e.g., the Inertia® Pedicle Screw System).

When used as a vertebral body replacement device, the HONOUR™ devices are indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors or trauma/fracture in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is intended for use with autograft or allograft and with supplemental internal fixation systems cleared for use in the thoracolumbar spine (e.g., the Inertia® Pedicle Screw System).

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K141376

Device Name

Facet Fixx™ facet screw system

Indications for Use (Describe)

The Facet Fixx System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle. For translaminar facet fixation, the screws are inserted through the lateral aspect of the spinous process, through the lamina, through the inferior articular process, across the facet joint and into the pedicle.

The Facet Fixx System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from C2 to S1 inclusive. The Facet Fixx System is indicated for treatment of any or all of the following:

- Degenerative disc disease (DOD) as defined by back pain of discogenic origins confirmed by history and radiographic studies
- Degenerative disease of the facets with instability
- Trauma (i.e. fracture or dislocation)
- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)
K141376

Device Name
Struxxure™ anterior cervical system

Indications for Use (Describe)

The Struxxure™ System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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